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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/069,148 | 06/24/2002 | Hiroyuki Hirai | Q68584 | 7696 |
| 23373 | 7590 | 07/27/2004 | EXAMINER | |
| SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | LANDSMAN, ROBERT S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,148

Applicant(s)

HIRAI ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. The Supplemental Response dated 5/3/04 has been entered into the record.
- B. The Amendment dated 4/13/04 has been entered into the record. This Amendment cancels claims 1-4 and adds new claims 5-16. Therefore, claims 5-16 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Priority Data

- A. The objection to the specification regarding referencing PCT/JP00/05615 in the priority claim in the first line of the specification has been withdrawn in view of Applicants' argument that this reference is not required (see the reference to "National Stage Applications" under MPEP 1893.03(c)). Regardless, Applicants have amended the first line of the specification to include the priority claim to the PCT.

3. Specification – new matter

- A. The amendment filed April 13, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants have amended page 24, lines 16-21 as well as Figure 4. The amendment renames the chemical compound "13, 14-dehydro-15-keto PGD2" with 13, 14-dihydro-15-keto PGD2."

Applicant is required to cancel the **new matter** in the reply to this Office Action.

4. Claim Objections

- A. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 6. Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 recites that the test substance selectively modulates human CRTH2 activity. It appears from the specification that the intent of the present invention is to selectively modulate the CRTH2 receptor as compared to the DP receptor (see page 5, line 10 – page 6, line 7 of the specification). Therefore, it is not understood to what "selectively modulates human CRTH2 activity" refers other than

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the DP receptor. Therefore, claim 7, which recites the DP receptor, would be a substantial duplicate of claim 6.

5. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 recites that the CRTH2 receptor is present on a cell. To show support for this new claim, Applicants have pointed to page 13, lines 23-24 of the instant specification (see page 7 of Applicants' Response dated 4/13/04) and the Japanese priority document, 2000-153172, specifically page 14, line 27 – page 15, line 1 (see also page 2 of Applicants' Response dated 5/3/04). However, this portion of the specification recites "cell expressing human CRTH2, or a cell fraction containing human CRTH2." There is no support for the limitation in claim 11 that the CRTH2 receptor is present *on a cell*. A cell expressing a human CRHT2 may be expressing the receptor internally and not on the cell surface. Even though claim 12 recites "down-modulation of CRTH2 molecules at a cell surface" and there is support for this limitation in the foreign priority document as cited by Applicants in the Response dated 5/3/04, it is not clear as to what "molecules" the phrase "CRTH2 molecules" encompasses (see paragraph E below under 35 USC 112, second paragraph). Therefore, the Examiner is not interpreting this phrase as encompassing the CRTH2 receptors themselves. Therefore, no support for "CRTH2 present on a cell" can be found, even when read in light of claim 12. Claims 12-14 are rejected since they depend from claim 11.

6. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of claims 1-4 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' cancellation of these claims and the fact that newly presented claims 5-16 do not recite terminology such as "properties," "effects" and "derivatives."

B. A rejection of claims 5-16 under 35 USC 112, first paragraph, is not being made regarding the scope of the term "human CRTH2" since the specification limits the encompassed receptor to that taught by Negata et al. (J. Immunol.) and WO 97/46677. This receptor is identical in both publications.

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7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 1-4 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' cancellation of these claims and the fact that newly presented claims 5-16 do not recite terminology such as "properties," "effects" and "derivatives."

B. A rejection of claims 5-16 under 35 USC 112, first paragraph, is not being made regarding the scope of the term "human CRTH2" since the specification limits the encompassed receptor to that taught by Negata et al. (J. Immunol.) and WO 97/46677. This receptor is identical in both publications.

8. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections of claims 1-4 under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' cancellation of these claims and the fact that newly presented claims 5-16 do not raise the issues recited on pages 4-5 of the Office Action dated 1/8/04. However, new rejections under 35 USC 112, second paragraph, appear below.

B. Claims 6, 8 and 9 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 6 recites "selectively modulates human CRTH2 activity." However, it is not clear as to what other, e.g. compound, receptor, etc., this CRTH2 activity is being compared. Claims 8 and 9 are also rejected since they depend from rejected claim 6.

C. Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The way the claims are worded, it appears that the claimed methods require a substance which already is known, for example, to "inhibit" (claim 8), or "promote" (claim 9) human CRTH2 activity. However, the purpose of the claimed methods is to, in fact, identify these properties of the test substances. As written, it appears that the claims are using test compounds in which these properties are already known (i.e. the claim must use a compound which, for example in claim 8, is already known to inhibit human CRTH2 activity). However, it cannot be determined that the test substance, for example, "inhibits human CRTH2 activity" before the substance has actually been tested. Therefore, the claims should be reworded to recite,

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for example in claim 8, "...wherein the activity is the inhibition of human CRTH2." It can then be determined whether or not the test substance meets the limitation of the claims.

D. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. It is not clear if the binding of the test substance is performed as part of the claimed method, or if the substance is identified "after the fact" as one which has bound to the CRTH2 receptor. If the intent of the claim is to identify the modulating ability of a test substance which is already known to bind to the CRTH2 receptor, then the claim is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps would be those which involve methods of binding the test substance to the receptor in order to determine its modulatory effect.

E. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The claim recites "CRTH2 molecules." It is not clear if this refers to the receptor itself, or to compounds or other proteins associated with the receptor. If the term is referring to specific compounds associated with the receptor, then the metes and bounds of this term is unclear.

F. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The claim recites "enhancement of migration." However, it is not clear what migration is being enhanced. For example, the claim could be referring to the migration of the receptor in the cell membrane, to various substances or proteins in a cell, or to the cells themselves. If the claim is intended to encompass only the migration of cells, it is not clear as to what cells "migration" refers. In the specification (page 17, line 4-6) Applicants only refer to an example in the prior art which states "see, e.g. a method described in Yokomizo, T. et al., Nature 387: 620-624, 1997." This is an example only and does not limit, or particularly point out and distinctly identify what migration is being enhanced.

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9. Claim Rejections - 35 USC § 103

A. Claims 11-14 are rejected under 35 USC 103(a) for the reasons already of record for canceled claims 1-4 on page 5 of the Office Action mailed 1/8/04. Applicants argue that the present invention receives priority of Japanese Application No. 11-236207, filed August 23, 1999 and Japanese Application No. 2000-153172, filed May 24, 2000 and that both of the priority applications were filed prior to the earliest effective filing date of the Li et al. publication.

This argument has been considered and is deemed persuasive in part. Therefore, the rejection is not being made over claims 5-10, 15 and 16. However, as seen in the above rejection under 35 USC 112, first paragraph, claim 11 recites new matter. Since the limitation that "CRTH2 is present on a cell" is not supported in any of these foreign documents, it does not receive priority to these dates. Therefore, Li et al. remains prior art for claim 11 (paragraph [0011] of Li et al. teaches the expression of CRTH2 on cells). Claims 12-14 are rejected since they depend from claim 11. Regarding claims 12-14, Li et al. recite measuring intracellular calcium concentrations ([0018]), and the use of mammalian cells, including CHO and HEK293 cells ([0109]). Since Applicants have not provided any arguments with respect to the actual teachings of Li et al. it is believed that all pertinent arguments have been addressed.

10. Conclusion

A. Claims 5, 15 and 16 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Advisory information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 23, 2004


ROBERT LANDSMAN
PATENT EXAMINER